K111863(1/3)

JUN 15 2012

510(k) Summary

Submitter information

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 39 62 80
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Contact name	Alexandra Razzhivina
Contact title	Regulatory Officer
Contact e-mail address	alexandra.razzhivina@materialise.be

Submission date

The date of the Traditional 510(k) submission is 28th June, 2011.

Submission information

Trade Name	Signature™ Planner Signature™ guides
Common Name	Hip prosthesis
Classification Name	- Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented - Prosthesis, Hip, Constrained, Cemented or Uncemented, Metal/Polymer - Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented - Prosthesis, Hip, Hemi-Femoral, Metal/Polymer, Cemented or Uncemented - Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous Cemented, Osteophilic Finish - Prosthesis, Hip, Semi-constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Primary product codes	LPH
Secondary product codes	LZO, KWZ, JDI, KWY, MAY, MEH

Predicate devices

Predicate Device	
Trade or proprietary or model name	SurgiCase
510(k) number	K073449
Decision date	04/16/2008
Product code	LLZ
Manufacturer	Materialise N.V.

Predicate Device	
Trade or proprietary or model name	Signature™ Personalized Patient Care System
510(k) number	K102795
Decision date	02/02/2011
Product code	JWH/OIY, MBH, OOG
Manufacturer	Materialise N.V.

Predicate Device	
Trade or proprietary or model name	Acumen Surgical Navigation System
510(k) number	K031454
Decision date	07/08/2004
Product code	HAW
Manufacturer	Biomet Manufacturing

Predicate Device	
Trade or proprietary or model name	Instrument
510(k) number	510(k) exempt (888.4540)
Decision date	NA
Product code	KIL
Manufacturer	Biomet Manufacturing

Device Information

Description of the device

The **Acetabular Guide System** consists of a software component, **Signature™ Planner** and a hardware component, **Signature™ guides** and is designed to assist the surgeon in the orientation of an acetabular cup.

The **Signature™ Personalized Patient Care System – Acetabular Guide System** can be used with the following Biomet acetabular systems and their respective compatible components: Bio-Clad™ All-Poly Cup (K810120 and K926107), Ranawat/Burstein™ All-Poly Cup (preamendment), RX-90™ Low Profile Shell (K920639 and K042989), Full Hemisphere Shell (K920640), Mallory/Head™ Shells (K861114, K921181, and K030055), Quadrant Sparing Shells (K920640 and K050124), Ranawat/Burstein™ Shells (K911685, K921277, and K050124), Regenerex™ Porous Titanium Shells (K052996), Regenerex™ Ringloc+ Shell System (K070369), Ringloc+ Acetabular System (K070369), Tri-Spike Pegged Shells (K970501 and K030055), Tri-Polar Shell (K991990), Universal Shells (K861433, K921301, and K030055), Vision™ Shells (K954417 and K030055), Freedom™ Constrained All-Poly Cups (K030047), M2a-Magnum™ with E1™ Active Articulation (K101336), and M2a-Magnum™ with ArComXL™ Active Articulation (K110555).

Functioning of the device

The **Acetabular Guide System** generates a pre-surgical plan based on MRI imaging data using the **Signature™ Planner** (software component). The software is then used pre-operatively by a qualified surgeon to inspect, fine-tune and approve the pre-surgical plan. Next,

Signature™ guides are designed and manufactured based on the approved pre-surgical plan. **Signature™ guides** are patient specific templates that transfer the pre-operatively determined pin locations and the planned acetabular cup orientation to the patient intra-operatively. The first surgical guide (Primary Acetabular Guide) is used to place two pins near the acetabular rim. A second surgical guide (Secondary Acetabular Guide) is then assembled to these pins and is used to recreate the pre-operatively determined acetabular cup orientation by positioning an alignment pin parallel to the planned cup insertion location. The surgeon may then place the acetabular cup implant in the pre-operatively determined location by aligning the inserter handle with the alignment pin held by the secondary acetabular guide. The alignment pin adaptor, an optional accessory, attaches to the cup inserter handle and interfaces with the alignment pin using a slot and a series of magnets. This orients the cup inserter handle parallel to the alignment pin during insertion of the acetabular cup.

Intended use

The **Signature™ Personalized Patient Care System – Acetabular Guide System** is intended to be used as a surgical instrument to assist in the orientation of acetabular cup components intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative MRI imaging scans.

The **Signature™ Personalized Patient Care System – Acetabular Guide System** can be used with all Biomet 510(k) cleared, legally marketed, primary acetabular systems and their respective components.

The **Signature™ guides** are intended for single use only.

Summary of technological characteristics

Device comparison showed that the proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

Performance data

Non-clinical tests

Accuracy performance testing and guide dimensional stability testing was performed to determine substantial equivalence. Testing verified that the accuracy and performance of the system is adequate to perform as intended.

Clinical data

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 15 2012

Materialise N.V.
℅ Ms. Alaxandra Razzhivina
15 Technologielaan
Leuven, Belgium 3001

Re: K111863
Trade/Device Name: Signature Planner, Signature Guides
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWZ, JDI, KWY, MAY, MEH
Dated: June 05, 2012
Received: June 07, 2012

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

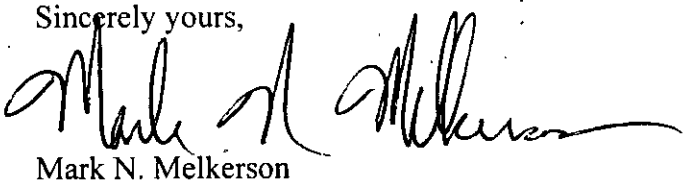
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111863 (1/1)

Indications for Use

510(k) Number (if known): K111863

Device Name: Signature™ Personalized Patient Care System – Acetabular Guide System (**Signature™ Guides, Signature™ Planner**)

Indications for Use:

The **Signature™ Personalized Patient Care System – Acetabular Guide System** is intended to be used as a surgical instrument to assist in the orientation of acetabular cup components intra-operatively using anatomical landmarks of the pelvis that are clearly identifiable on preoperative MRI imaging scans.

The **Signature™ Personalized Patient Care System – Acetabular Guide System** can be used with all Biomet 510(k) cleared, legally marketed, primary acetabular systems and their respective components.

The **Signature™ guides** are intended for single use only.

Prescription Use _ X ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111863